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DINSMORE & SHOHL LLP
FIFTH THIRD CENTER, ONE SOUTH MAIN STREET
SUITE 1300
DAYTON, OH 45402-2023

EXAMINER	
PARK, HAEJIN S	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/576,356
Filing Date: December 11, 2006
Appellant(s): BOTT ET AL.

Timothy W. Hagan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on December 6, 2011 appealing from the Office action mailed on April 7, 2011.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 72 and 74 – 91 are pending and rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,545,086 B1	Kosal	04-2003
2003/0180281 A1	Bott et al.	09-2003
4,655,767	Woodard et al.	04-1987

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 72 and 74 – 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosal (US Patent no. 6,545,086 issued on April 8, 2003) in view of Bott et al. (US Pre-Grant Publication no. 2003/0180281 A1 published on September 25, 2003) as evidenced by Woodard et al. (US Patent no. 4,655,767 issued on April 7, 1987).

Concerning claim 72, Kosal is directed to oil-in-water (O/W) emulsions for "medical applications such as transdermal drug delivery patches, … , or to hold an active agent such as a fungicide to the skin surface", or for formulating mascaras and sunscreens (col.1 ll.20-23; col.5 ll.23-24). The O/W emulsions comprise an oil or silicone phase with pressure sensitive adhesives (PSAs), in a continuous water phase, and a surfactant (Title; abstract; claim 1). Kosal further teaches avoidance of hydrocarbon based, i.e. lipophilic, solvents in medical applications such as transdermal drug delivery patches (col.5 ll.26-28). The aqueous or hydrophilic phase of the O/W emulsion contains a carrier referred to as a "thickener" including a water soluble polymer such as polyvinyl alcohol and xanthan gum (col.5 ll.4-13), which one of ordinary skill in the art will appreciate modifies diffusion or release of components within the emulsion.

Kosal does not expressly teach incorporating a protein active agent in the hydrophilic phase of the O/W emulsion.

Bott et al. is directed to sustained release preparations for topical administration of active agents including protein active agents. Bott et al. teaches water-in-oil (W/O) emulsions comprising a protein active agent in an aqueous phase and a carrier such as polyvinyl alcohol, wherein the external, i.e., hydrophobic phase may be a silicone PSA (title; abstract; paras.0002, 0008, 0041).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kosal and Bott et al. and prepare O/W emulsions of Kosal comprising the protein active agent of Bott et al. in the hydrophilic phase and a silicone PSA in the hydrophobic phase as taught by Kosal and Bott et al.

One would have been motivated to do so because of the following reasons:

(i) Kosal teaches that the silicone PSA in O/W emulsion provides controlled tack and lubrication and greater durability, free of hydrocarbon based solvents, and is useful in transdermal drug delivery patches (col.5 ll.14, 19-27), which the skilled person would recognize as advantageous properties in prolonged topical applications;

(ii) Kosal teaches that using endblocking agents is especially useful for preventing loss of adhesion when the silicone PSA is in contact with amines (col.3 ll.33-43), which are present in protein active agents of Bott et al.;

(iii) Kosal teaches that preferably the O/W emulsions are prepared by phase inversion of an W/O emulsion (col.4 ll.24-32) such as of Bott et al.; and

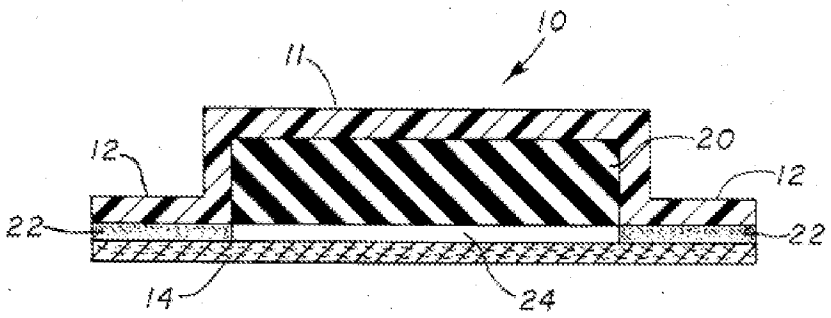
(iv) Bott et al. discloses that using emulsions comprising a silicone PSA (such as of Kosal) and an aqueous phase with protein active agent and a carrier achieves sustained release of the protein active agent (paras.0001, 0002, 0041).

Concerning claims 87 – 88, Kosal and Bott et al. do not explicitly disclose a multi-layer dressing comprising a controlled-release layer, an adhesive layer, and an additional layer. However as noted above Kosal teaches using the O/W emulsion composition of its invention in “transdermal delivery patches" (col.4 l.24). Such transdermal drug delivery systems comprising

at least three layers were "well known to those skilled in the art" at the time of the invention as evidenced by Woodard et al. (col.3 ll.33-50), which Kosal references (col.3 l.38).

Woodard et al. teaches transdermal drug delivery device embodiment with amine-resistant silicone adhesives (title; abstract; Figs. 1-2). Specifically the transdermal device shown in Figure 2 of Woodard et al. comprises a drug reservoir layer 20, an adhesive layer 22, and additional layers comprising a backing layer 14 and polymeric material layers 11 and 12 (Fig. 2).

Fig. 2



Concerning claim 88, when the drug reservoir layer is adjacent to the substrate, i.e., skin, with layer 11 or 12 removed, the backing layer 14 is adjacent to the adhesive layer 22 and spaced from the drug reservoir layer as recited, and with layer 14 removed, polymer layer 12 is disposed adjacent to the adhesive layer 22 and spaced from the drug reservoir layer. Thus in view of the rejection of claim 72 based on Kosal and Bott et al. above and the state of the art as evidenced by Woodard et al., the multilayer controlled composition in the form of a multi-layer dressing in claims 87 – 88 are not patentable.

Concerning claim 89, Kosal does not expressly teach a multi-layer dressing comprising dry controlled-release layer of the O/W emulsion.

Bott et al. however teaches preparation of patches comprising silicone PSA emulsion comprising protein active agent and carrier solution, which is spread onto a Mylar® sheet, dried, and then cut into patches (Examples 7-10; paras.0085, 0089, 0093, 0097).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kosal and Bott et al. and dry the layer comprising composition of instant claim 72.

One would have been motivated to do so because Bott et al. is drawn to transdermal delivery of protein active agents via patches. In particular the multi-layer patches of Bott et al. were tested for enzymatic stability or loss of activity, and were shown to provide more stable means of storing and releasing the enzyme (paras.0088, 0092, 0096, 0100). Accordingly claim 89 is not patentable in view of the rejection of claim 72 based on Kosal and Bott et al. above.

(10) Response to Argument

Claim 72 as representative of claims 72 and 74 – 86

Appellants' argument (1)

Appellants first argue that Kosal "is not directed to controlled delivery of a protein active" (Brief at 5, heading).

The examiner does not dispute that Kosal does not expressly mention a protein active. However, Kosal does disclose controlled delivery of an active agent, albeit not a protein active agent, and also states that using endblocking agents "reduces sensitivity of the adhesive to loss of adhesion in contact with reagents such as amines" (col.3 ll.39-43). One of ordinary skill in the art thus would have known that Kosal can be used with amine-group agents. Bott et al. teaches

delivery of various protein actives using a W/O emulsion comprising a silicone PSA in the hydrophobic phase.

Appellants further argue that in Kosal the active agent is "either separate from the PSA and held to the substrate in a conventional manner with the pressure sensitive adhesive, or the active agent is physically mixed with the PSA and adhered to the substrate", and furthermore Kosal is "silent concerning whether the active agent resides in the oil phase or the aqueous phase of the PSA". (Brief at 5, bottom para.)

Appellants do not cite which embodiment has the active agent "separate from the PSA", and examiner was not able to identify any such embodiment among Kosal's Examples 1 through 8. Furthermore, Example 5 contained the active agent Kathon® CG biocide, diluted with water and mixed with oil-in-water PSA emulsion (col.7 ll.15-18). Thus the skilled person will appreciate that the active agent biocide was in the water or hydrophilic phase of the emulsion, as recited in instant claim 72.

Appellants also argue that Bott et al. "is directed to a water-in-oil emulsion, unlike both the claimed composition and that of the primary reference" (Brief at 5, heading, and at 6, top para.).

While the examiner agrees that a W/O emulsion is not identical to a O/W emulsion, Kosal teaches that its O/W emulsion, comprising a silicone PSA in the hydrophobic phase (as in Bott et al.) is preferably prepared from W/O emulsion comprising silicone PSA in the hydrophobic phase (col.4 ll.24-32; col.5 ll.20-26) which Bott et al. teaches (para.0041).[1] Therefore one of ordinary skill in the art would have been further motivated to combine Kosal and Bott et al. Obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007).

Appellants also state that in Bott et al., a hydrophilic phase containing the active agent is emulsified and then "dried, resulting in droplets of the aqueous phase containing the active agent entrapped within the continuous silicone phase" (Brief at 6, second para.; see also Brief at 8-9, and 10, first full para.). Appellants then refer to Bott et al.'s explanation of possible mechanisms of release such as creation of "pores, crevices, cracks, or fissures within the silicone matrix" (para.0035 of Bott et al.).

[1] Prior to the amendment dated February 18, 2011, even Appellants' claim 72 had recited "formed by mechanical inversion of a water-in-oil emulsion".

First, Appellants do not cite specific paragraphs and it is not seen that the "dried" emulsion still contains the active in an aqueous phase. Examples 7 – 10 concern patches which were coated with the W/O emulsion and then made to "dry or cure completely" (paras.0085, 0089, 0093, 0097). Thus it is not seen that Bott et al. discloses a dried emulsion that still contains an aqueous phase containing the active agent. Rather, once dried or cured completely, the active agent with any trace water or hydrogen would be dispersed within the hydrophobic phase. Instant claim 89 is directed to such an embodiment.

Second, regarding the mechanism of controlling release, Kosal teaches that the hydrophilic phase of the O/W emulsion contains a thickener such as xanthan gum or polyvinyl alcohol (col.4 ll.4-13) which the skilled person would appreciate modifies release of the active agent. The instant claims recite that the composition "comprises" the recited components and thus indicates that other ingredients may be present which further the controlling or sustaining effect.

Furthermore, a hydrophobic phase containing the silicone PSA would undergo formation of "pores, crevices, cracks, or fissures" whether in an O/W or W/O emulsion if present in sufficient quantity. However instant claim 72 does not limit the concentration of the hydrophobic phase. Accordingly, absent evidence, it is not seen that the composition of Kosal prepared by phase inverting the composition of Bott et al. would result in a different mechanism, not rate, of release-control. In short, the difference between W/O emulsion of Bott et al. versus O/W emulsion of Kosal, where Kosal teaches transdermal drug delivery and phase inversion of a W/O emulsion containing a silicone PSA such as of Bott et al., does not overcome prima facie obviousness.

Moreover, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Here, the examiner's position is that the skilled person would have found teaching, suggestion, and motivation to combine Kosal and Bott et al. based, in addition to the factors discussed above, on the fact that Kosal teaches phase inversion of a water-in-oil emulsion such as of Bott et al. (which recommends using pressure-sensitive adhesives as the oily phase) as a preferred method of preparing the oil-in-water adhesive composition of its invention, for use in durable, transdermal patches (col.4 ll.24-32; col.5 ll.20-26).

Appellants next argue that examiner's motivation to combine Kosal and Bott et al. is "not supported by the evidence of record" because controlled tack, lubrication, and greater durability "already reside" in the composition of Bott et al. (Brief at 6-7).

Contrary to Appellants' assertion, Bott et al. does not appear to disclose that the W/O emulsions also provide controlled tack, lubrication, and greater durability. Moreover to the extent that Appellants are implying that the W/O emulsions of Bott et al. are expected to possess such similar properties as the O/W emulsions of Kosal, such a view only supports rather than negates a finding of prima facie obviousness.

Appellants' argument (2)

Appellants next argue that "(2) Kosal does not teach or suggest the controlled release of an active agent." (Brief at 7). Kosal describes using the adhesive composition to secure contact of an active agent against the skin (id. at 8), and "there is a material difference between locating an active agent in an oil-in-water emulsion to control the release of that agent (claimed invention) versus simply holding an active agent against a patient's skin (Kosal)" (Brief at 9).

However, Kosal's disclosure includes using the O/W emulsion in "transdermal delivery patches", i.e., "to hold an active material such as a fungicide to the skin surface" (col.5 ll.23-26), because the composition provides "controlled tack and lubrication" and "greater durability, protective qualities, water resistance and barrier properties" (col. 5 ll.15-16, 20-22). To a skilled person, the holding of an active agent, controlled lubrication, and the greater durability, protective qualities, water resistance and barrier properties would indicate that Kosal's composition is useful in preparations for extended or prolonged stay on the substrate surface.

Prolonged contact indicates release, at the least at the interface between the composition and the substrate. Notably Appellants' own disclosure is limited to holding the patch in a cell culture (Example 1, Fig. 2, pre-grant publication US 2007/0218115 A1 at para.0066 "a patch sample was attached on top of the cell"). One having ordinary skill in the art would appreciate, as reflected in Applicants' own disclosure, that holding of the active agent against a substrate results in release of that active agent into the substrate.

Further, Kosal teaches that the hydrophilic phase of its oil-in-water emulsion contains a thickener or a carrier such as polyvinyl alcohol or xanthan gum (col.4 ll.4-13) which the skilled person would recognize affects release or solubility of components in the composition. The instant claims only recite controlled or sustained release generally, and no minimum duration of such release that would be clearly beyond the scope of Kosal's disclosure to the skilled person. Thus it is not seen that Kosal's teaching is solely limited to adhesive applications, to the exclusion of any sustained release application as Appellants contend.

In addition to these teachings in Kosal, as stated before and in the rejection above Bott et al. teaches sustained release topical preparations of water-in-oil emulsions where the oily phase is a silicone pressure sensitive adhesive: "[T]he silicone matrix may be comprised of a silicone pressure sensitive adhesive (silicone PSA), such as a silicate resin in silicone polymers, which can be solvent based or hot-melt, ..." (para.0041). Accordingly the obviousness rejection was not made on the ground that Kosal alone teaches attaining sustained release through the pressure sensitive adhesives. The rejection was rather based on Kosal combined with Bott et al. which teaches sustained release matrices comprising silicone PSA as well as the protein active agent recited in claim 72.

Appellants' argument (3)

Appellants next argue that "Kosal does not address, nor does he solve, any problem relating to the controlled release of an active agent from an adhesive composition" (Brief at 9). Regarding examiner's discussion of Kosal's teaching on using a thickening agent as modifier in the O/W emulsion, Appellants contend that the presence of a thickening agent teaches nothing about the controlled release of an active agent (id. 10).

In response it is noted that prior art is assessed from the perspective of one having ordinary skill in the art, not an uninformed layman. One having ordinary skill in the art would appreciate that a thickening agent affects movement and therefore the release of an active agent from the medium in which it is present. For example a drop of food dye travels in plain water much faster than in a thicker medium such as a milk. Thus the fact that Kosal teaches using a thickening agent indicates that the O/W emulsion can be modified to suit a given application, including slowing the movement and thus extending the release of the active agent contained in the O/W emulsion.

Appellants next argue concerning the statement in page 11 of the Final Rejection — "absent evidence, it is not seen that" the composition of Kosal prepared by phase inverting the composition of Bott et al. would result in a different mechanism, not rate, of release control — that it contains legal and factual error (Brief at 10). The legal error charged appears to be that "it is not an applicant's burden to provide evidence to negate obviousness; to the contrary, it is the Office's legal burden to establish evidence that supports the conclusion of obviousness" (id.).

As stated in the Advisory Action of July 26, 2011, what the MPEP requires is: "[t]he examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness," depending on which Applicant may present evidence of nonobviousness to overcome the prima facie case. MPEP 2142. Thus "factual support" and "evidence" are not synonymous. Moreover the Office is without the resources to conduct testing and gather evidence of obviousness of the subject matter it examines for patentability.

The factual error that Appellants appear to charge is that Bott et al. teaches mechanisms of release of the active agent from its W/O emulsion, while Kosal's "only description of the use of an active is to use the pressure sensitive adhesive to cover an active and hold it against the surface of the skin or to mix an active into the PSA for the purpose of holding the active in place", and thus the two references do not coincide in the respective teaching regarding the release of the active agent.

As discussed above, examiner disagrees with Appellants and maintains that, to a skilled artisan, Kosal discloses that its O/W emulsion is used to contact with skin and release an active agent over time. Simply put, the fact that Kosal and Bott et al. do not use identical or similar words and teach the same mechanism of action does not undercut an obviousness rationale.

Appellants' argument (4)

Appellants assert that "(4) Applicants are not attacking the references individually". Appellants argue that each of the advantages that Kosal teaches in its O/W emulsion is irrelevant to controlled release of any active agent or not required (as is the case for "(c) free of hydrocarbon based solvents") (Brief at 11-12).

But as noted before obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

Appellants next argue that in Kosal the phase inversion is "performed with no active agent in the aqueous phase because Kosal either has no need for any active agent, or mixes in the active agent after forming the emulsion" (Brief at 12).

But as noted above Kosal teaches the Kathon® biocide in the hydrophilic phase, as claimed in instant claim 72. Moreover it is a composition claim, and merely pointing out one particular method of preparing the composition that it not in the cited prior art, is not seen to overcome the rejection. Also, Kosal teaches using the O/W emulsion in mascara and sunscreen formulations (col.5 ll.21-22), which means that the emulsion is mixed with the active agent —a colorant or ultraviolet screening agent.

Appellants finally argue concerning claim 72, that "[w]hen stripped of all speculation" the rejection is based on speculation and impermissible hindsight.

However , it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Here, Kosal teaches O/W emulsions comprising a hydrophobic phase with a silicone PSA and a hydrophilic phase with an active agent, prepared preferably from phase inversion of a W/O emulsion, and Bott et al. teaches W/O emulsions comprising a hydrophobic phase with a silicone PSA and a hydrophilic phase with a protein active agent, which comprise the prior art knowledge one of ordinary skill in the art would have gleaned as required by *In re McLaughlin*.

Claims 87 – 88

Appellants argue that the rejection does not provide a motivation for combining the references or propose "modifications or substitutions proposed by Examiner", and that combination with Woodard would render the PSA of Kosal and Bott superfluous (Brief at 13). Moreover Woodard et al. nowhere states that the "drug-impregnated elastomer layer" contacts the skin as alleged by the Examiner (id.).

As noted above, Kosal references Woodard et al., which explicitly states that the transdermal patches such as that shown in Figure 2 were "well known to those skilled in the art", i.e., as of 1987 when Woodard et al. issued. Kosal teaches using its O/W emulsions in transdermal patches (col.5 ll.22-23) and references Woodard et al. (col.3 l.38) as well as other transdermal patch prior art. Kosal specifically states that "[t]he pressure sensitive adhesive

emulsion of the invention delivers performance properties such as controlled tack and lubrication and can be used for example in …medical applications such as transdermal drug delivery patches" (col.5 ll.14-16, 23-25). A reasonable person will thus appreciate that it would have been obvious to use the composition of Kosal in the "well known" patch of the type specifically described in Woodard et al. To contend that the rejection is deficient for lack of an explicit statement of a "motivation for combining Woodward with the other reference teachings" (Brief at 13) is elevating form over substance and imposing a standard of determining obviousness not from the perspective of one of ordinary skill in the art, but of an uninformed and oblivious layperson.

Concerning the statement about "drug-impregnated elastomer layer" contacting the skin, note that Figure 2 shows "space 24" through which the drug "comes into contact with the wearer's skin" (Woodard et al. at col.3 ll.23-25).

Claim 89

Appellants repeat the arguments that Kosal does not disclose controlled release, Bott et al. is directed to W/O emulsion, and that the two are not combinable (Brief at 13-14).

Examiner maintains that Kosal and Bott et al. are combinable for the teaching, motivation, and suggestion discussed in the Grounds of Rejection, namely that Kosal teaches O/W emulsions comprising a hydrophobic phase with a silicone PSA and a hydrophilic phase with an active agent, prepared preferably from phase inversion of a W/O emulsion, and Bott et al. teaches protein active agent in an W/O emulsion comprising a hydrophobic phase with a silicone PSA and a hydrophilic phase with an active agent. Furthermore one would have been motivated to do so because of the following reasons:

(i) Kosal teaches that the silicone PSA in O/W emulsion provides controlled tack and lubrication and greater durability, free of hydrocarbon based solvents, and is useful in transdermal drug delivery patches (col.5 ll.14, 19-27), which the skilled person would recognize as advantageous properties in prolonged topical applications;

(ii) Kosal teaches that using endblocking agents is especially useful for preventing loss of adhesion when the silicone PSA is in contact with amines (col.3 ll.33-43), which are present in protein active agents of Bott et al.;

(iii) Kosal teaches that preferably the O/W emulsions are prepared by phase inversion of an W/O emulsion (col.4 ll.24-32) such as of Bott et al.; and

(iv) Bott et al. discloses that using emulsions comprising a silicone PSA (such as of Kosal) and an aqueous phase with protein active agent and a carrier achieves sustained release of the protein active agent (paras.0001, 0002, 0041).

Moreover in view of Bott et al. disclosure of removing water from the W/O emulsion, i.e., "dry or cure completely" to prepare transdermal protein drug patches stable for over 6 months (paras.0088, 0092, 0096, 0100), claim 89 is obvious over Kosal in view of Bott et al.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/H. Sarah Park/
Examiner, Art Unit 1615

Conferees:

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612